

- Dr. Joshua Copel
- Professor of Obstetrics, Gynecology and Reproductive Sciences, & Pediatrics Yale University School of Medicine
- High Risk Obstetrics, prenatal diagnosis and therapy
- Board Certified Maternal-Fetal Medicine.
- President-Elect of American Institute of Ultrasound in Medicine.

Disclosures

- Consultant to a number of ultrasound companies (none of them seeking OTC Doppler)
- Advised Oxford about a hand-held Doppler device intended only for professional use.
 - Received a free hand-held device donated to a clinic for indigent patients in Kingston, Jamaica

Disclosures

- SGE for FDA OB-GYN devices panel
 - No related reviews

Expertise

- Prenatal diagnosis of fetal cardiac anomalies
- Management of fetal arrhythmias
- Limited to that aspect of the Petition

Petition

- 29 July 2002, Dr. Russel Thomsen:
- “... [T]here are at least anecdotal reports of life-saving interventions being instituted because of the home use of doppler fetoscopes.”

Petition

- 8 Sept 2003:
- “Anecdotal (cases reported by consumers back to Doppler fetoscope sellers, renters or manufacturers) instances exist where pregnancy intervention has occurred because of this home use leading to live or healthy babies.”
- “To the contrary, there are at least anecdotal reports of life-saving interventions being instituted because of the home use of Doppler fetoscopes. Furthermore, this would, potentially put in their hands an item which might save the life of their unborn babies.”

Implications

- There are abnormalities of fetal cardiac rhythm that occur with some frequency
- These are easily recognizable to the layperson
- Some intervention available that would reduce morbidity or mortality once this dysrhythmia is recognized.

Fetal Arrhythmias

- Many number of neonates have benign rhythm extrasystoles
- Largest series of cases of common fetal arrhythmias (Copel JA, Liang RI, Demasio K, Ozeren S, Kleinman CS: The clinical significance of the irregular fetal heart rhythm. Am J Obstet Gynecol 2000;182:813-819).

Fetal Arrhythmias

- 600 fetuses referred for irregular heart rates
- 55% had no rhythm abnormality
- Low frequency of significant rhythm disturbances.
- Little benefit would accrue to fetuses from OTC availability of hand-held Doppler devices in terms of detection of dangerous arrhythmias

False Alarms

- Detection of the maternal heart rate
 - Maternal rate usually 60-90
 - Fetal heart rate 120-160
- Mistaken emergencies

85358

081

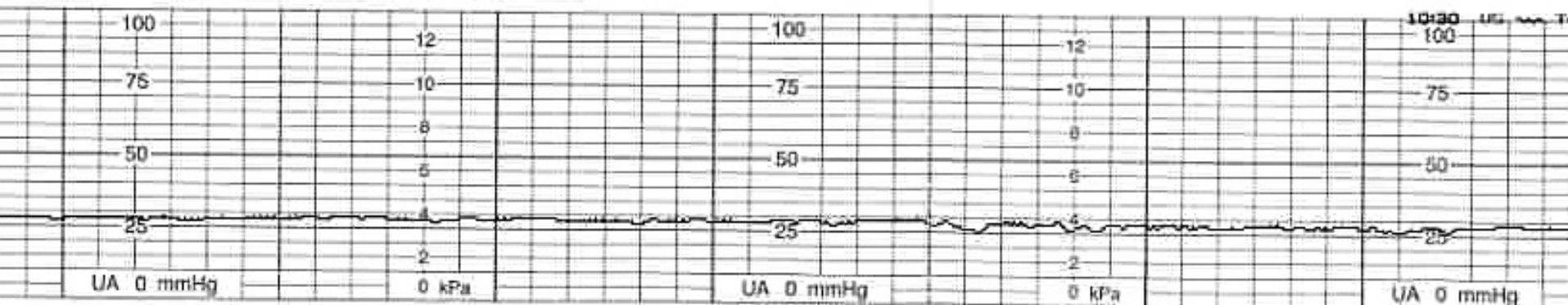
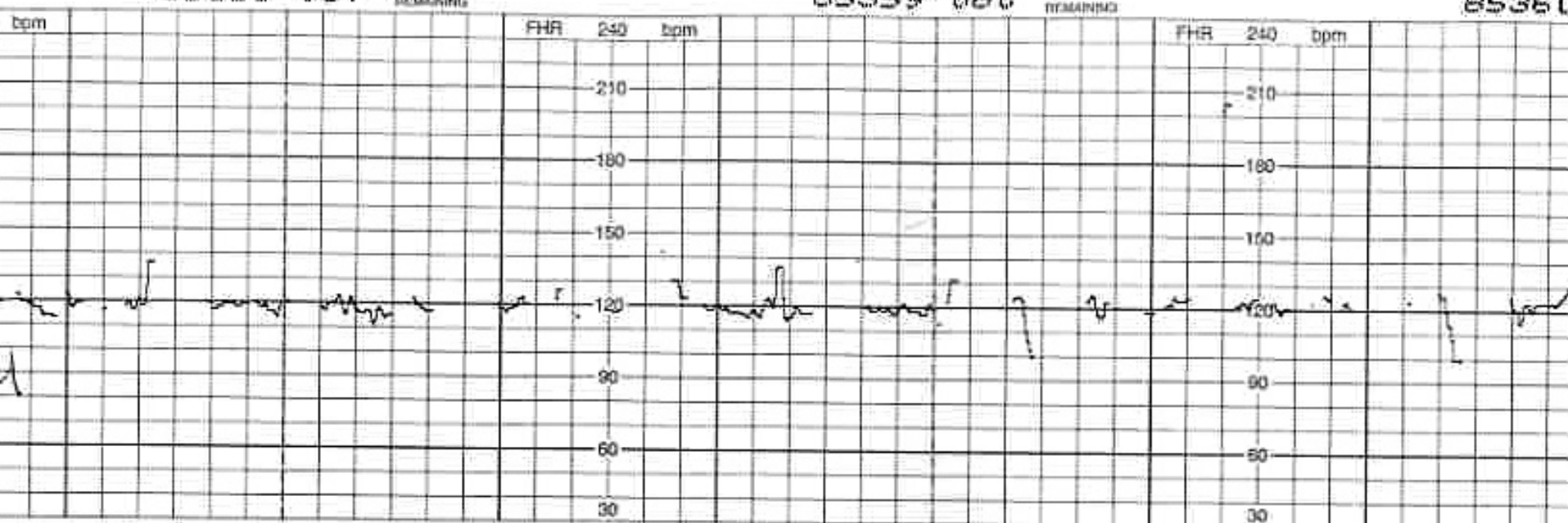
PAGES
REMAINING

85359

080

PAGES
REMAINING

85360



Periodic Changes

- “Late” decelerations in labor
- Often subtle alterations from baseline
- Difficult to distinguish even by experienced observers looking at electronic fetal monitors.
- Can untrained laypersons detect them by auscultation alone?

Periodic Changes

- Most are uncommon outside of labor
- “Variable” decelerations
 - Normal variants in second trimester
 - Incidental detection will lead to more harm than good
 - Unnecessary testing without benefit

Summary

- No clear benefit to the consumer from OTC availability of hand-held fetal Doppler devices
- Potential for harm
- I must therefore oppose the current petition

Thank you